K102526

OCT 2 2 2010

Pascal Company, Inc.

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510(k) SUMMARY (AS REQUIRED BY SECTION 807.92c)

Submitted/Prepared by: Vincent M. Tentarelli
Pascal Company, Inc.
2929 NE Northup Way
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USA

Title: Quality Assurance Manager

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Date Prepared: October 19, 2010

Manufacturer/Applicant: Pascal Co., Inc.

Site Address: 2929 NE Northup Way
Bellevue, WA 98004

Mailing Address: PO Box 1478
Bellevue, WA 98009-1478

Est. Reg. No.: 3011632

Trade Name: BLO_2X Oxygen Blocker

Common Name Tooth Shade Resin

Classification Name: Material, Tooth Shade, Resin

Device Class: Class II

Device Panel: Dental

Regulation Number: 21 CFR 872.3690

Product Code: EBF

Substantial equivalence: **BLO_2X Oxygen Blocker** is substantially equivalent to the originally classified device described in CFR 872.3690 "Material, Tooth Shade, Resin." It is also substantially equivalent and nearly identical to (for example) the following product that is currently on the market, having been cleared by 510(k):

Predicate Product

Trade Name: **DeOx®**, Oxygen Barrier Viscous Solution

510(k) Number: K941065

Owner: Ultradent Products, Inc.

Address: 505 W. 10200 So.
South Jordan, UT 84095

Substantial Equivalence/Comparison to Predicate

The document, "Guidance on the CDRH Premarket Notification Review Program, June 30, 1986 (K86-3)" was used to determine substantial equivalence.

Intended Use

BLO_2X Oxygen Blocker: **BLO_2X Oxygen Blocker** has the same intended use, "to prevent negative contour in areas where oxygen inhibition of resin polymerization results in premature material loss," as cleared by the 510(k) process, as listed above.

DeOx®: Use **DeOx®** to prevent negative contour in areas where oxygen inhibition of resin polymerization results in premature material loss.

Use it before curing composites or luting to prevent the oxygen inhibition layer from forming. **DeOx®** allows removal of luting resins closer to the final contour before curing, thus eliminating the need to address a large excess of cured composite or luting cement.

Technological Characteristics

BLO_2X Oxygen Blocker: The technological characteristics for this product are the same as those for the predicate device and other products currently on the market except for minor variations in the same or similar components.

BLO_2X Oxygen Blocker is a clear, glycerin-based gel containing a viscosity-inducing agent, producing a gel with similar viscosity characteristics to the predicate product.

DeOx®: According to product literature and the MSDA, the predicate product, **DeOx®** is a glycerin-based viscous solution.

Descriptive Information

BLO_2X Oxygen Blocker: Descriptive information provided shows that the materials from which Pascal Co., Inc.'s **BLO_2X Oxygen Blocker** is made are substantially equivalent to (nearly identical with some) those of similar products, used for identical purposes, currently on the market.

Comparison to Predicate Product Description

BLO_2X Oxygen Blocker: **BLO_2X Oxygen Blocker** is a clear, viscous, glycerin-based gel designed to prevent oxygen inhibition layer formation on the surface of resin materials when they are polymerized.

The use of **BLO_2X Oxygen Blocker** during the application of the last composite layer is to prevent the oxygen from inhibiting the material's ability to reach final polymerization. The presence of oxygen during this final phase increases the risk of the loss of the final layer of composite material. This may result in a premature material loss of the applied composite material.

DeOx®: **DeOx®** is a clear, viscous, glycerin-based solution designed to prevent oxygen inhibition layer formation on the surface of resin materials when they are polymerized.

Indications for Use

BLO_2X Oxygen Blocker: **BLO_2X Oxygen Blocker** is intended to prevent negative contour in areas where oxygen inhibition of resin polymerization results in premature material loss. Use it before curing composites or luting to prevent the oxygen inhibition layer from forming. **BLO_2X Oxygen Blocker** allows removal of luting resins closer to the final contour before curing, thus eliminating the need to address a large excess of cured composite or luting cement.

DeOx®: Use **DeOx®** to prevent negative contour in areas where oxygen inhibition of resin polymerization results in premature material loss.

Use it before curing composites or luting to prevent the oxygen inhibition layer from forming. **DeOx®** allows removal of luting resins closer to the final contour before curing, thus eliminating the need to address a large excess of cured composite or luting cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Vincent M. Tentarelli
Quality Assurance Manager
Pascal Company, Inc.
2929 N.E. Northup Way
Bellevue, WA 98004

OCT 2 2 2010

Re: K102526
Trade/Device Name: BLO_2X Oxygen Blocker
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 1, 2010
Received: September 2, 2010

Dear Mr. Tentarelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pascal
Company, Inc.

INDICATIONS FOR USE

OCT 2 2 2010

510(k) Number (if known): K102526

Device Name: **BLO_2X Oxygen Blocker**

Indications for Use:

BLO_2X Oxygen Blocker is intended to prevent negative contour in areas where oxygen inhibition of resin polymerization results in premature material loss. Use it before curing composites or luting to prevent the oxygen inhibition layer from forming. **BLO_2X Oxygen Blocker** allows removal of luting resins closer to the final contour before curing, thus eliminating the need to address a large excess of cured composite or luting cement.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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